REMARKS

Claims 1-33 are currently pending in this application. Claims 10, 13-22, and 24 have been withdrawn and Applicants submit claims 1-9, 11-12, 23, and 25-33 for reconsideration.

The Office rejected claims 1-9, 11-12, 23, 25, and 26-33 under 35 U.S.C. § 101 for an asserted lack of utility, stating that "it is completely unknown what biological processes the instant protein or its underlying encoding nucleic acids are associated with or involved in." *See* Office Action of November 20, 2003, at 4. Furthermore, the Office stated:

> There is absolutely no evidence of record or any line or reasoning that would support a conclusion that the nucleotides of the instant application can be used for diagnosis, prevention and treatment of diseases or disorders as stated on pages 3-4 of the specification. Until some actual and specific significance can be attributed to the protein identified in the specification as IGS1, or the gene encoding it, the instant invention is incomplete.

Id. at 5-6.

Applicants traverse this rejection because they have shown the biological processes affected by the IGS1 gene and an actual and specific significance for the IGS1 gene of the claimed invention, as demonstrated in the attached Declaration submitted under 37 C.F.R. § 1.132. This Declaration supports the utility of the invention that is provided on page 4 of the specification, which states: "In particular the uses include treatment of psychiatric and CNS disorders, especially movement disorders, such as tics, tremor, Tourette's syndrome, Parkinson's disease, Huntington's disease, dyskinesias, dystonia and spasms." Specification at 4, lines 20-22.

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Briefly, the Declaration provides the results of a study showing that IGS1 mRNA expression is differentially regulated when a model of Parkinson's disease is created in the brains of rats. When brain lesions are induced that mimic Parkinson's disease, the levels of IGS1 mRNA are reduced. IGS1 mRNA was shown in these studies to be regulated by midbrain dopamine innervation. In addition, the data indicate that the cellular compartments that express IGS1 mRNA are directly or indirectly involved in the information processing of dopaminergic afferents to the striatum. Because it is known that this region of the brain receives dopaminergic projections from the substantia nigra pars compacta, which is affected in Parkinson's disease, IGS1 appears to have a biological role in that disease. This link to Parkinson's disease demonstrates the utility of the IGS1 gene as a tool for diagnosing it or as part of an assay for selecting ligands that can be used to treat or prevent it. Thus, the IGS1 gene of the claimed invention is involved in the dopaminergic pathways of the brain and has a significant and substantially credible utility in diagnosing, preventing, and treating Parkinson's disease.

Furthermore, the results provided in the Declaration show that IGS1 mRNA is expressed in regions of the brain that are associated with limbic function, such as the ventral striatum, and so may be involved in psychiatric disorders affected by the limbic system. Therefore, another significant and substantially credible utility of the claimed invention is diagnosing, preventing, and treating psychiatric disorders affected by limbic function.

In light of these utilities, Applicants request that the rejection under 35 U.S.C. § 101 be withdrawn.

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The Office also rejected claims 1-9, 11-12, 23 (in part), 25, and 26-33 (in part) under 35 U.S.C. § 112, first paragraph, for an asserted lack of enablement due to the asserted lack of a utility. Applicants traverse this rejection because, as discussed above, the claimed invention has specific and substantial utility, and therefore, there is no basis for the rejection. For example, a utility of the invention is diagnosing Parkinson's disease. Further, Applicants have provided a protocol that would allow one skilled in the art to screen for agonist or antagonist ligands for IGS1. *See* Specification at Example 3, pp. 38-40. Therefore, Applicants have provided an enabling description of a utility of the claimed invention. Accordingly, Applicants request that the rejection under 35 U.S.C. § 112, be withdrawn.

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
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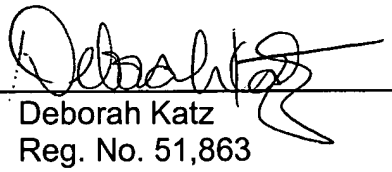
Dated: February 19, 2004

By: 

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Attachments: Declaration under 37 C.F.R. § 1.132.

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